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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,641	10/03/2001	Chin-Shiou Huang	ASPI-002/03US	2745

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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 08/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,641

Applicant(s)

HUANG, CHIN-SHIOU

Examiner

Jon D Epperson

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File Copy
-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,9,10 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 11.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on May 23, 2003 (Paper No. 8).

Priority Claims

2. The priority filing date of February 18, 2000 for DIV application 09/507,299 (now abandoned) is acknowledged.

Status of the Claims

3. Claims 1-27 are pending in the present application.
4. Applicant's response to the Restriction and/or Election of Species requirements in Paper No. 11 is acknowledged (Applicant elected Group I, claims 1-19) and claims 20-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see below i.e., Response to Restriction and/or Election of Species).
5. Please note: Applicant's elected species (matrix material = acrylamide) was found in the art. Furthermore, Applicant's *specifically* elected species (template molecule = palmitoyl-LKKATNE) was searched and was not found in the prior art. Thus, the search was expanded to

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non-elected species, which *were* found in the prior art, see rejections below. Also, see MPEP § 803.02 (emphasis added):

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. *The prior art search, however, will not be extended unnecessarily to cover all nonelected species.* Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

6. Claims 4-5, 9-10 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected species, the requirement having been traversed in Paper No. 6 (see below i.e., *Response to Restriction and/or Election of Species*).

7. Therefore, claims 1-3, 6-8 and 11-19 are examined on the merits in this action.

Response to Restriction and/or Election of Species

8. Applicant's election of Group I (claims 1-19) *with traverse* in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement with regard to Group II, the election has been treated as an election without traverse (MPEP § 818.03(a)) with regard to Group II.

9. With regard to Group III, Applicant's traversal is on the grounds that examining Groups I and III would place no serious burden on the examiner because the Groups are classified into the

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same class and subclass and the Groups encompass overlapping subject matter (see Paper No. 8, page 6, last paragraph).

10. These arguments were fully considered but were not found persuasive. As stated in the Restriction Requirement dated April 26, 2003 (see Paper No. 7, paragraphs 1-3), these inventions (Groups I-III) have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Here, Group II requires “oriented” imprint cavities i.e., divergent subject matter that is not required by Group I. Therefore, this does create an undue search burden for the Office. Furthermore, Applicant has not stated on the record that Group III would be an obvious variant of Group I.

11. Applicant’s election of species in Paper No. 11 (see attached interview summary) *with traverse* is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)).

12. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

13. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, “the list may not be

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incorporated into the specification but must be submitted in a separate paper.” Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.

14. The references listed on applicant’s PTO-1449 form have been considered by the Examiner. A copy of the form is attached to this Office Action.

Specification

15. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

16. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant’s cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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17. Claims 1-3, 6-8 and 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claim 1**, the phrase “wherein a substantial fraction of the imprint cavities are localized at or near the surface of the matrix material” is vague and indefinite. For example, it would appear to the Examiner that all “cavities” must be “at the surface” of the matrix material or else they would not be a cavity i.e., a cavity is defined as an indentation or hole in a surface. Applicants are requested to clarify. Therefore, claim 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. For **claim 1**, the term “substantial fraction” is vague and indefinite. For example, Applicants’ specification defines “substantial” as “more cavities are localized at or near the surface of the matrix material than are located at internal regions [i.e., >50%]”, but this contradicts their later definition stating that the surface imprints can be only “20%” (see specification, page 11, paragraph 2).

Furthermore, Applicants define the “cavities” as being at OR “near” the surface wherein the word “near” is a relative term, which renders the claim indefinite and/or unclear. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See also MPEP § 2173.05(b).

Applicants are requested to clarify and/or correct. Therefore, claim 1 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

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C. For **claim 8**, the phrase "terminal portion of the macromolecule" is vague and indefinite especially when the macromolecule is not a "linear" molecule. For example, the "terminal portion" with respect to nucleic acids and proteins may be interpreted as be in 5', 3', N-terminal, or C-terminal but it is not clear how the term would apply to cyclic peptides, etc. Therefore, claim 8 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

D. **Claims 2-3** recites the limitation "the surface imprint" in the first line. There is insufficient antecedent basis for this limitation in the claim. The Examiner recommends "the surface imprint composition" like in claims 6-19. Therefore, claims 2-3 and all dependent claims are rejected under 35 USC 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-3, 6-8 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnold et al (U.S. Patent No. 5,310,648) (Date of Patent is **May 10, 1994**).

For **claim 1**, Arnold et al (see entire document) discloses molecular imprint compositions that selectively bind predetermined molecules or biological particles (see Arnold et al, abstract), which anticipates claim 1. For example, figure 1 shows a

“template” molecule binding to a polymerized “cavity” (i.e., an imprint) at the surface of the polymerized material (see also figures 2-3, showing the formation of imprint cavities corresponding to a two-dimensional lipid surface i.e., corresponds to Applicant’s immobilized template molecules; see also column 8, paragraph 2, “[t]he ... imprinted matrices have a large surface area accessible for protein binding and can be used, for example, in chromatographic separation, in drug delivery, and for biosensors”).

For *claim 2-3*, Arnold et al discloses polymers including, for example, styrene, ethylene glycol, dimethacrylate (e.g., see Arnold et al, column 2, paragraphs 2-4; see also figure 1; see also column 3, last two paragraphs; see especially column 4, line 23; see also column 8, paragraph 1).

For *claims 6-8, 11-16*, Arnold et al discloses templates including DNA, oligonucleotides, proteins, peptides and polysaccharides wherein all different sizes and orientations would be immediately envisioned (e.g., see Arnold et al, see column 4, lines 51-61, “The template molecule can be ... small organic molecules ... larger molecules such as peptides, oligonucleotides, proteins, DNA, and polysaccharides. Such larger macromolecules are referred to herein as ‘macromolecules’”).

For *claim 17-19*, Arnold et al discloses lipid bi-layers with various substituents attached including proteins, porphyrins, etc, which would fall within the scope of a spatially identifiable array with at least two different template molecules wherein at least one of said template molecules corresponds to a macromolecule (see Arnold et al, figure 3b; see also column 7, line 60).

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19. Claims 1-3, 6-8 and 11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yan et al (U.S. Patent No. 5,587,273) (Date of Patent is **December 24, 1996**), which incorporates by reference Mosbach et al (U.S. Patent No. 5,110,833) (Date of Patent is May 5, 1992).

For *claim 1*, Yan et al (see entire document) discloses molecular imprint arrays on silicon wafers for use as biosensors, which anticipates claim 1 (see Yan et al, abstract; see also column 1, lines 39-45 and column 2, lines 56-62, "The present invention provides novel molecularly imprinted polymers and methods for making such polymers. The imprinted molecules allow the manufacture of thin films disposed on surfaces, such as the surface of a silicon wafer") (see also Yan et al, column 2, lines 22-34 referring to Mosbach et al for general methods of producing molecular imprint materials that include, for example, polymerization of methyl methacrylate, and the use of molecular imprints to separate compounds).

For *claim 2-3*, Yan et al discloses many different polymers including, for example, polystyrene, acrylics, polyolefins (e.g., see Yan et al, claim 13; see also column 8) (see also Yan et al, column 2, lines 22-34 referring to Mosbach et al for general methods of producing molecular imprint materials that include, for example, polymerization of methyl methacrylate).

For *claims 6-8, 11-16*, Yan et al discloses that "virtually any imprinting molecule can be used" (e.g., see Yan et al, column 10, last paragraph; see also tables 2-3) (see also Mosbach et al, column 3, lines 13-29 disclosing that the molecular imprinting materials

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can be used in the same way as antibodies in immunological assays, which include ELISA (one or two dimensional array assay of pluralities of analytes) and that the corresponding antigens may be peptides, proteins or glycoproteins, for example)..

For *claim 17-19*, Yan et al discloses that a variety of templates can be used (see Yan et al, column 14, paragraph 3) (see also Mosbach et al, column 3, lines 13-29 disclosing that the molecular imprinting materials can be used in the same way as antibodies in immunological assays, which include ELISA (one or two dimensional array assay of pluralities of analytes) and that the corresponding antigens may be peptides, proteins or glycoproteins, for example).

20. Claims 1-3, 17, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi et al (Takeuchi, T.; Fukuma, D.; Matsi, J. "Combinatorial Molecular Imprinting: An Approach to Synthetic Polymer Receptors" *Anal. Chem.* **1999**, 71, 285-290).

For *claim 1*, Takeuchi et al (see entire document) discloses combinatorial molecular imprinting, which anticipates claim 1 (see Takeuchi et al, abstract; see also figures 1 and 4-6 wherein a plurality of the cavities are localized at or near the surface of the matrix material that is located at the bottom of an array of glass vials).

For *claim 2-3*, Takeuchi et al discloses several different polymers including methacrylic acid, ethylene glycol dimethacrylate, methyl methacrylate (e.g., see Takeuchi et al, page 286, column 2, paragraph 2; see also page 286, column 1, last two paragraphs).

For *claim 17, 19*, Takeuchi et al discloses that a library of templates can be used
(see Takeuchi et al. figures 4-6).

Double Patenting

Claim Rejections – 35 USC § 101

21. A rejection based on double patenting of the “same invention” type finds its support in the language of 35 USC 101 which states that “whoever invents or discovers any new and useful process ... may obtain a patent therefore ...” (Emphasis added). Thus, the term “same invention,” in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

22. Claims 1-3, 6-8 and 11-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 6-8 and 11-19 of copending Application Nos. 20020164643 A1 and 20020110901 A1. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Non-Statutory

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claim 1-3, 6-8 and 11-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6-8 and 11-19 of U.S. Patent Application Nos. 20020045275 A1 (referred to as '275) and 20020045274 A1 (referred to as '274).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1986).

Although the conflicting claims are not identical, they are not patentably distinct from each other (compare the present application to Patent Application Nos. '275 and '274 showing that all of the features are identical except for the fact that neither '275 or '274 claims "surface imprints"). However, both '275/'274 and the present application claim a "spatially identifiable array" (see claim 19 of all applications), which is defined in Applicant's specification as a "surface imprint" (e.g., see figure 3b of '275).

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It is acknowledged that the double patenting rejection discusses portions of the specification (and not just the patented claims); however, MPEP 800 set forth that disclosure can be used as a dictionary for claim terminology; and that “those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent” (MPEP § 804).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Other Related Applications

25. It is noted that Application serial No.10/443613 is not available to the examiner and may contain claims over which the pending claims may be rejected and/or provisionally rejected under 35 U.S.C. 101 double patenting or nonstatutory double patenting. This Application is undergoing pre-exam processing. The Examiner is unable to view the allowed claims at present. Applicant is requested to provide a copy of the allowed claims in response to this office action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

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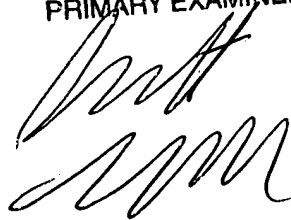
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Jon D. Epperson, Ph.D.

August 19, 2003

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Bennett Celsa', written over the printed name.